

109045v

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Summary of Safety and Effectiveness

AUG 26 2009

In accordance with 21 CFR 807.92, the following information constitutes the summary of safety and effectiveness for *Insuflow*[®].

SUBMITTER'S NAME: LEXION Medical LLC
ADDRESS: 5000 Township Parkway
St. Paul, MN 55110
CONTACT PERSON: Bernard (Bud) Horwath
TELEPHONE NUMBER: 651-361-8041
FAX NUMBER: 651-351-8001
DATE OF SUBMISSION: 18 February 2009

1. Identification of device

Proprietary Name: *Insuflow*[®]

Common Name: Laparoscopic Insufflator Gas Conditioner

Classification Status: Class II per regulations 884.1730

Product Code: HIF

2. Equivalent devices

LEXION Medical believes that *Insuflow*[®] is substantially equivalent to the following devices:

Insuflow[®], K063546

CarbonAid, K052125

Insuflow[®] is the same gas conditioner insufflator accessory device as cleared under 510(k) K063546 and has essentially the same intended use as the predicate devices.

3. Description of the Device

The *Insuflow*[®] device is a single use device that attaches to the outlet port of an insufflator or other regulated CO₂ source and is designed to warm and humidify the CO₂ gas stream prior to insufflation into the cardiothoracic, vascular or abdominal surgical cavity. The *Insuflow*[®] device consists of a disposable filter heater/humidifier tubing set and a control module that houses the control and safety circuits for the system.

Regulated CO₂ gas flows into the *Insuflow*[®] device, through the in-line filter, continues along the tube to enter the *Insuflow*[®] device cassette that contains the heating element and humidification media, through a tube that connects via a Luer lock connector to an insufflation needle/trocar and finally flows into the patient's surgical cavity.

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Insuflow[®] 510k

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4. Intended use

Insuflow® is a gas conditioner accessory device for use in minimally invasive surgery, including thoracoscopic, laparoscopic and endoscopic vein harvesting surgical procedures, intended to heat, humidify and filter a CO₂ gas stream for insufflation of the surgical cavity.

5. Technological characteristics, comparison to predicate device.

Technically, the Insuflow® is identical to the Insuflow® cleared for market in 510(k) K063546 and essentially equivalent to the other predicate. The indications for use for the Insuflow® are patterned after the predicate devices and supported by an extensive collection of literature references.

6. Discussion of performance testing.

Extensive performance testing has been conducted to assure that the Insuflow® performs in accordance with its specifications and applicable standards. Details of that testing were provided in 510(k) K063546 and are summarized in Section 5.

7. Conclusion

Based on a comparison to the predicate devices and information provided, it is the conclusion of LEXION Medical that Insuflow® is substantially equivalent to devices already on the market being used for these applications (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

Insuflow®

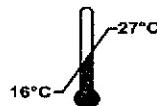
(1) Gas Conditioning Device

(1) 10mL Luer Lock Syringe

Required Translations...

Intended Use: Insuflow® is a gas conditioner accessory device for use in minimally invasive surgery, including thoracoscopic, laparoscopic and endoscopic vein harvesting surgical procedures, intended to heat, humidify and filter a CO₂ gas stream for insufflation of the surgical cavity.

CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a physician.



Patent 5,411,474 and Patent 6,068,609

LEXION

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Bernard Horwath
Regulatory Consultant
LEXION Medical, LLC
5000 Township Parkway
ST PAUL MN 55110

AUG 26 2009

Re: K090456

Trade/Device Name: *Insuflow*[®]
Regulation Number: 21 CFR §884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: II
Product Code: HIF
Dated: August 5, 2009
Received: August 6, 2009

Dear Mr. Horwath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

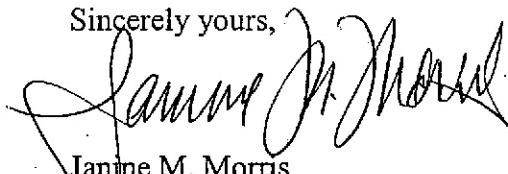
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

A. INDICATIONS FOR USE

510(k) Number K090456

Device Name: **Insuflow®**

Indications for Use:

Insuflow® is a gas conditioner accessory device for use in minimally invasive surgery, including thoracoscopic, laparoscopic and endoscopic vein harvesting surgical procedures, intended to heat, humidify and filter a CO₂ gas stream for insufflation of the surgical cavity.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K090456

Prescription Use
(Per 21 CFR 801.109)

OR Over the Counter Use

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